

Notice of Allowability

Application No.

09/920,425

Examiner

Peter J Vrettakos

Applicant(s)

LEE, BRUCE B.

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to RCE dated 3-16-04.
2. ☒ The allowed claim(s) is/are 1-4,6-17,19-26 and 30-33.
3. ☐ The drawings filed on _____ are accepted by the Examiner.
4. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 - a) ☐ All b) ☐ Some* c) ☐ None of the:
 1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

* Certified copies not received: _____.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.

THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.

5. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
 6. ☒ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
 - (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
 - 1) ☐ hereto or 2) ☐ to Paper No./Mail Date _____.
 - (b) ☒ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date 4-28-04.
- Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).
7. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

1. ☒ Notice of References Cited (PTO-892)
2. ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3. ☐ Information Disclosure Statements (PTO-1449 or PTO/SB/08),
Paper No./Mail Date _____
4. ☐ Examiner's Comment Regarding Requirement for Deposit
of Biological Material
5. ☐ Notice of Informal Patent Application (PTO-152)
6. ☐ Interview Summary (PTO-413),
Paper No./Mail Date _____
7. ☒ Examiner's Amendment/Comment
8. ☒ Examiner's Statement of Reasons for Allowance
9. ☐ Other _____

EXAMINER'S AMENDMENT

Claims 32 and 33 are newly added.

Claims 5,18, and 28 have been cancelled.

An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it **MUST** be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with David Park on 4-28-04.

The application has been amended as follows:

Claims 27 and 29 are cancelled without prejudice.

The following is an examiner's statement of reasons for allowance: The Applicant has filed an RCE dated 3-16-04. A declaration has also been filed in which the inventor Bruce Lee, MD (who performs the surgery disclosed in the claims) has testified toward the patentability of using an intra-ultrasound probe to carry out **direct** uterine fibroid ablation using a **separate** ablation probe.

The Office has presented in prior rejections the combination of separate methods one involving direct ablation of the tumor (Behl, Edwards) and one involving ablation of the tumor's peripheral blood supply (Savage). In response, the Declaration underscores

the differences in targeting blood supply to tumors instead of direct tumor targeting (electrode completely inside the tumor) for ablation. For example, direct ablation avoids the problem of targeting healthy peripheral tissue that targeting peripheral tumor blood supply does not. As a result combining the two separate methods (direct versus indirect ablation) to create a rejection has been proven inappropriate.

The Declaration also asserts commercial success, which is construed by the Examiner as indicative of patentability of using an intra-ultrasound probe to carry out **direct** uterine fibroid ablation using a **separate** ablation probe. The method's implementation has been successful and indicates the non-obviousness of the claimed method.

Claims 1, 12, 30, and 33 are all independent. Each include language toward three or more electrodes being entirely inserted into a pelvic tumor aided visually by a separate intra-abdominal ultrasound probe, followed by targeted ablation.

An update search was performed by the Examiner that did not yield new art for rejections. As a result the independent claims (1,12,30, and 33) are allowable as they all disclose language toward a method of three or more electrodes being entirely inserted into a pelvic tumor aided visually by a separate intra-abdominal ultrasound probe, followed by targeted ablation.

For the sake of clarity on the record, newly found prior art is discussed below. The differences in the patents and the application's claims are highlighted. Hascoet et al. (5,234,004) discloses a method in which a microwave emitting probe (20) and a

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separate rectal ultrasound ("echograph") probe (82) are used to target a prostate (pelvic tumor). See figure 1. If the patent made any suggestion of using instead an intra-abdominal ultrasound probe (in lieu of rectal probe), then a 35 USC 103 rejection would be appropriate. However, no such suggestion is found.

Oppelt et al. (5,759,162) discloses prostate treatment using external ultrasound imaging and treatment, which involves two separate probes. If the patent made any suggestion of using instead an intra-abdominal ultrasound probe (in lieu of an external probe) and a microwave/radiofrequency probe (instead of an ultrasound probe), then a 35 USC 103 rejection would be appropriate. However, no such suggestions are found.

Holdaway et al. (6,217,518) discloses in figure 4 a method in which a cryogenic probe (16) and a separate rectal ultrasound probe (20) are used to target a prostate (10, pelvic tumor). If the patent made any suggestion of using instead an intra-abdominal ultrasound probe (in lieu of rectal probe) and a microwave/radiofrequency probe (instead of a cryogenic probe), then a 35 USC 103 rejection would be appropriate. However, no such suggestions are found.

Rittman et al. (6,575,969) discloses in figure 11 a method in which an RF probe (1103) and a separate external ultrasound probes are used to target a tumor (1102). If the patent made any suggestion of using instead an intra-abdominal ultrasound probe (in lieu of external probe), then a 35 USC 103 rejection would be appropriate. However, no such suggestion is found.

The Drawings filed 7-31-01 are not acceptable. Submission of formal drawings is required.

This application claims benefit of 60/224,191 dated 08/09/2000.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Peter J Vrettakos whose telephone number is 703 605 0215. The examiner can normally be reached on M-F 9-6.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Linda C Dvorak can be reached on 703 308 0994. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Pete Vrettakos
April 28, 2004

PV

Michael Peffley
MICHAEL PEFFLEY
PRIMARY EXAMINER